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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,308	09/16/2003	Robert Sutherland	005513P017	4329

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Daniel E. Ovanezian
BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP
Seventh Floor
12400 Wilshire Boulevard
Los Angeles, CA 90025-1026

EXAMINER

CHAO, ELMER M

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3737

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/664,308	Applicant(s) SUTHERLAND ET AL.	
	Examiner ELMER CHAO	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-21,24,31-43 and 53-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-21,24,31-43 and 53-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/26/2009 & 6/2/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Acknowledgement is made of the amendment filed 1/8/2009.
2. Acknowledgement is made of the Information Disclosure Statements filed 1/26/2009 & 6/2/2009.

Claim Objections

3. **Claims 33 and 34** are objected to because of the following informalities:
Regarding claim 33, it is unclear what means or functional language is being proposed since claim 31 already recites the in vivo landmark having a sensor device. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. **Claims 15-21, 24, 31-43, and 53-60** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Regarding claim 15, the limitation "at least one of which is other than and not physically attached to the sensor", the scope of which is not supported by the originally filed Specifications. Regarding claim 31, the limitation "using an

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in vivo landmark having a sensor device" is not supported by the Specifications. Applicants pointed to claim 33 as support for the limitation but claim 33 does not recite the same limitation.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 15, 31, 32, 35, 36, and 54** are rejected under 35 U.S.C. 102(b) as being anticipated by Holupka et al. (U.S. 5,810,007).

Regarding **claims 31, 32, 35, and 36**, Holupka et al. teach a method of imaging a plurality of markers and an in vivo landmark (prostate gland) in a first imaging modality CT (abstract; col. 3, lines 53-64; col. 4, lines 13-15, and figures 2 & 3); correlating a position of the in vivo landmark relative to at least one of the plurality of markers (col. 3, lines 61-67; fig. 2); imaging the plurality of markers in a second modality (col. 3, line 62), wherein the in vivo landmark is not imageable in the second modality (col. 1, lines 54-56); and determining the position of the in vivo landmark relative to at least one of the plurality of markers based on the correlating (col. 3, lines 61-67).

Specifically regarding claim 31, the actual landmark is not imaged by the x-ray (col. 1, lines 54-56). Thus, the markers are imaged by both modalities but

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the landmark is not. Therefore, it doesn't matter which imaging modality is labeled as "first" or "second" because the limitations are satisfied either way with one modality being able to image the landmark and one modality not being able to image the landmark.

Regarding **claims 15 and 54**, Holupka et al. teach the limitations as discussed above, including a sensor with markers (see abstract, refer to ultrasound probe and fiducials). The markers are not the sensor itself since the sensor can be considered the portion of the ultrasound probe not acting as the fiducials.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. **Claims 15-21, 24, 43, 53, 59, and 60** are rejected under 35 U.S.C. 103(a) as being unpatentable over Grzeszczuk et al. (U.S.2002/0077543 A1) in view of Scarantino et al. (U.S. 6,402,689 B1).

Regarding **claims 15, 16, 21, 24, 53, 59, and 60**, Grzeszczuk et al. teach a method comprising: situating a device in a body (para [0056], refer to surgical tools); and identifying a position of the device relative to an internal coordinate system using an imaging technique (para [0056], refer to 'registration'), wherein

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the internal coordinate system is based on a plurality of markers located in the body having an imageable marker property (para [0052] & para [0056]), wherein identifying comprises identifying the position relative to the at least one of the plurality of markers (para [0053]); and tracking the device over time (abstract)

Grzeszczuk et al. teach the limitations as discussed above. Grzeszczuk et al. also teach the device being tracked to be a medical instrument inside of a patient (abstract). Grzeszczuk et al. fail to explicitly teach the medical instrument being a sensor device. However, Scarantino et al. teach a medical instrument that is a radiation sensor device (abstract). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of invention to modify Grzeszczuk et al. to teach the medical tool to be a radiation sensor device in order to quantify the amount of radiation received at a tumor (for motivation see abstract).

Regarding **claim 18**, Grzeszczuk et al. teach the limitations as discussed above but fail to explicitly teach the sensor device having a length less than approximately 26 millimeters. However, Scarantino et al. teach implantable devices that have reduced size (col. 21, lines 31-33). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to use a very small implantable device having a length less than 26 millimeters in order to implant it with a needle (for motivation see col. 21, lines 31-33).

Regarding **claim 19**, Grzeszczuk et al. teach identifying the position relative to an anatomical landmark (para [0052] refer to "skeletal landmark").

Regarding **claim 20**, Grzeszczuk et al. teach the limitations as discussed above but fail to explicitly teach identifying the position of the device relative to an organ. However, Grzeszczuk et al. do teach using anatomical landmarks for image registration. These landmarks would then show up on the display while the medical instrument is being tracked. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to use certain organs as landmarks as a matter of design choice since different medical procedures would involve different in vivo locations which may cause certain organs with better visibility and proximity to be used for registration purposes.

Regarding **claims 17 and 43**, Grzeszczuk et al. teach the limitations as discussed above but fail to explicitly teach implanting the sensor through injection. However, the methods of implanting a medical sensor will vary based on the type of sensor and the location at which the procedure is performed. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Grzeszczuk et al. to include injecting the sensor as a matter of design choice since the instant application also lacks any mention of a specific advantage of implanting a sensor via injection methods (for example see para [0040] in the Specifications of the instant application). Furthermore, Scarantino et al. teach implanting a device through injection (col. 21, lines 31-33). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the method to include injection through a needle in order to minimize invasiveness.

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9. **Claims 33, 34, and 37-42** are rejected under 35 U.S.C. 103(a) as being unpatentable over Holupka et al.

Regarding **claims 33 and 34**, Holupka et al. teach that the in vivo landmark is a sensor device (col. 3, lines 50-55; fig. 2) and comprises at least one of the plurality of markers (col. 3, lines 61-67; fig. 2).

Regarding **claims 37, 38, 40, and 41**, Holupka et al. teach a second imaging modality except for the modality of being kV imaging or MV imaging. It is well known in the art that kV imaging and MV imaging provide quality images and excellent localization. It would have been obvious to a person of skill in the art at the time of the invention to use kV imaging or MV imaging as the second imaging modality to achieve quality images with excellent target localization.

Regarding **claim 39**, Holupka et al. teach a first imaging modality except for the modality being MRI. It would have been obvious to a person of skill in the art at the time of the invention to use magnetic resonance imaging as the first imaging modality since it is well known in the art that using magnetic resonance imaging for the first imaging modality to achieve quality images with excellent target localization.

Regarding **claim 42**, Holupka et al. teach a second imaging modality except for the modality being ultrasound when the first imaging modality is magnetic resonance imaging. It would have been obvious to a person of skill in the art at the time of the invention to use magnetic resonance imaging as the first imaging modality since it is well known in the art that using these imaging techniques in the manner provide high quality images and excellent localization.

10. **Claims 55-58** are rejected under 35 U.S.C. 103(a) as being unpatentable over Holupka et al. in view of Scarantino et al.

Regarding **claim 55**, Holupka et al. teach the limitations as discussed above but fail to explicitly teach sensing a radiation dose. However, Scarantino et al. teach sensing a radiation dose (abstract). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of invention to modify Holupka et al. to include sensing radiation order to quantify the actual amount of radiation received at a tumor (for motivation see abstract).

Regarding **claim 56**, Holupka et al. teach the limitations as discussed above but fail to explicitly teach sensing the temperature of the body. However, Scarantino et al. teach sensing temperature during radiation therapy (col. 11, lines 1-4). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of invention to modify Holupka et al. to including sensing temperature in order to determine penetration depth (for motivation see col. 11, lines 1-4).

Regarding **claims 57 and 58**, Holupka et al. teach the limitations as discussed above but fail to explicitly teach implanting the sensor through injection. However, the methods of implanting a medical sensor will vary based on the type of sensor and the location at which the procedure is performed. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Holupka et al. to include injecting the sensor as a matter of design choice since the instant application also lacks any mention

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of a specific advantage of implanting a sensor via injection methods (for example see para [0040] in the Specifications of the instant application). Furthermore, Scarantino et al. teach implanting a device through injection (col. 21, lines 31-33). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the method to include injection through a needle in order to minimize invasiveness.

Response to Arguments

11. Applicant's arguments filed 1/8/2009 have been fully considered but they are not persuasive.

12. Regarding Applicants' arguments with respect to claims 31, Applicants argue that Holupka et al. do not teach monitoring in vivo at least one physiological parameter of the body (page 6, 3rd paragraph – page 7, 1st paragraph). However, Examiner asserts that the term 'physiological parameter' is very broad and can encompass a wide range of parameters. At the very least Holupka et al. teach monitoring the location of the prostate relative to a landmark (see abstract), which is considered a physiological parameter. Applicants further argue "the Patent Office cannot have it both ways" (page 7, 1st paragraph).

However, Examiner contends that just because the claim 31 requires monitoring a physiological parameter and correlating a position of an in vivo landmark does not preclude the position of the in vivo landmark being used as the physiological parameter, especially since Holupka et al. teaches that this landmark is the prostate location (inarguably a physiological parameter). If Applicants intend on

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interpreting the claim as having separate and non-overlapping steps then it should be described as such.

13. Regarding Applicants' arguments with respect to claim 15, Applicants argue that Holupka and Grzeszczuk et al. do not teach "...at least one of which is other than and not physically attached to the sensor" (page 7, 1st paragraph - page 8 second paragraph). However, as described above this limitation does not meet the written description requirement. Even assuming *arguendo*, Examiner has explained in the obviousness rejection that Grzeszczuk et al. teaches a plurality of markers used for the internal coordinate system (see at least para [0056], refer to "fiducials").

14. Regarding Applicants' arguments with respect to claim 16, Applicants argue that the references do not teach injecting a sensor using a needle (page 9, second paragraph). However, Examiner notes that this limitation is recited in claim 17 and not claim 16, and a proper obviousness rejection had been provided regarding this limitation.

15. Regarding Applicants' arguments with respect to claim 18, Applicants argue that one would not combine Scarantino with Grzeszczuk since it would defeat the purpose of using LEDs that must remain external to the body. However, by modifying the sensor to be a reduced size capable of being injected, the purpose of using LEDs that remain external to the body would not be affected. Applicants also argue that Grzeszczuk does not motivate one of ordinary skill in the art to conceive of a sensor for injection by a needle. However, this

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limitation is addressed in the rejection of claim 17 and at least Scarantino et al. provides sufficient motivation for the modification.

16. Regarding Applicants' arguments with respect to claim 21, Applicants argue that Grzeszczuk et al. do not teach the tracking of the position of the sensor device over time and as the body moves (page 9, last paragraph). Examiner disagrees and asserts that Grzeszczuk et al. do teach tracking the position of the sensor device as the body moves. Since the tool is tracked, it would involve being tracked over the course of time by definition. Examiner informs Applicants that a living human body always contains internal movement and would satisfy the latter part of the limitation. Applicants also argue that Grzeszczuk's technique does not enable real-time DRF for the sake of target movement monitoring. However, this limitation is not required by the claims. Applicants argue that Grzeszczuk et al. requires periodic re-registration principle of operation and thus teaches against tracking the position of a sensor. However, the term "tracking" does not preclude the use of re-registration and thus Applicants' cannot regard the re-registration as sufficient evidence of teaching away from the step of tracking the position of the sensor.

Conclusion

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is

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filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELMER CHAO whose telephone number is (571)272-0674. The examiner can normally be reached on Mon-Thurs 11am-9pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/
Supervisory Patent Examiner, Art
Unit 3737

/E. C./
Examiner, Art Unit 3737